

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

ERFINDERGEMEINSCHAFT UROPEP
GbR,

Plaintiff,

V.

ELI LILLY AND COMPANY, and
BROOKSHIRE BROTHERS, INC.,

Defendants.

CASE No. 2:15-cv-01202-WCB

PLAINTIFF UROPEP’S SUBMISSION REGARDING WILFULNESS

UroPep submits this notice of authority and its position on willfulness pursuant to the Court's request.

ARGUMENT

I. Willfulness Standard

Willfulness is “a classical jury question of intent.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1341 (Fed. Cir. 2016) (citation omitted). In *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 136 S. Ct. 1923, 1933-34 (2016), the Supreme Court moved from a “rigid formula” for enhanced damages under § 284 to a framework requiring courts to “take into account the particular circumstances of each case,” *id.* Post-*Halo*, proving willfulness requires a party to meet the “preponderance of the evidence” standard and not the previous “clear and convincing” standard. *Halo Elecs., Inc.*, 136 S. Ct. at 1934.

To support a willfulness finding, the totality of the circumstances must show egregious conduct. The Supreme Court has characterized “egregious” behavior as including infringement conduct that is “deliberate.” *Halo Elecs., Inc.*, 136 S. Ct. at 1932-33. Such conduct includes “whether [Lilly] made a good-faith effort to avoid infringing the patent, whether [Lilly] reasonably believed it had a defense to infringement at the time it engaged in the infringing conduct, or whether [Lilly] relied on a legal opinion that was well supported and believable.” *See Polara Eng'g, Inc. v. Campbell Co.*, -- F. Supp. 3d --, 2017 WL 754609, at *12 (C.D. Cal. Feb. 27, 2017) (applying *Halo*).

At bottom, “[w]illfulness require[s] that [UroPep] prove by a preponderance of the evidence that [Lilly] knew, *or it was so obvious that [Lilly] should have known*, that its actions constituted infringement of a valid and enforceable patent.” *Barry v. Medtronic, Inc.*, No. 1:14-CV-104, 2017 WL 1197854, at *12 (E.D. Tex. Jan. 25, 2017) (emphasis added) (citing *Halo*). The reasonableness of Lilly's litigation positions cannot overcome its willful infringement. *Id.*

Rather, a willfulness finding is warranted if Lilly acted while “*knowing or having reason to know* of facts which would lead a reasonable man to realize his actions are unreasonably risky.” *Halo*, 136 S. Ct. at 1933 (internal citation and quotation marks omitted).

II. Lilly’s Infringement Is Willful

Looking at the totality of the circumstances, a reasonable jury could find that Lilly’s infringement of the ’124 patent is willful. Lilly knew of the ’124 patent in October 2014 when it received a letter from UroPep’s counsel (the “Larsen Letter”). Dkt. 189-23; April 18, 2017, Stip.¹ The Larsen letter informed Lilly that its sale of Cialis appeared to require Lilly to take a license to the ’124 patent. Dkt. 189-23. Lilly never responded to the letter.

That Lilly was infringing, and continues to infringe, is clear from the face of the patent. The patent covers the method of treating BPH with a selective PDE5 inhibitor. That is what Lilly induces when it promotes Cialis for BPH and ED+BPH, a selective PDE5 inhibitor, for that very purpose.

Having been told that it needed a license to continue selling Cialis for its BPH indications, Lilly did nothing. The ’124 patent claim 1 is simple and Lilly’s label repeats the claim language nearly verbatim. The ease with which Lilly could have determined (or did determine) that its promotion and sale of Cialis infringes the ’124 patent demonstrates that “it was so obvious that [Lilly] should have known, that its actions constituted infringement of a valid and enforceable patent.” *Barry*, 2017 WL 1197854, at *12. A simple comparison of claim 1 of the ’124 patent and the Cialis label shows how obvious it would have been to Lilly – a

¹ On April 18, 2017, the Court read the following stipulation to the jury: “Lilly first had actual notice of the existence of the ’124 patent around October 9, 2014, when it received a letter from Kim Larsen, UroPep’s counsel. There were no further communications between the parties until UroPep filed this lawsuit.” Ex. A, Trial Tr. at 455:16-21 (4/18/2017).

sophisticated pharmaceutical company with an experienced team of intellectual property experts – had it investigated the matter in light of the Larsen Letter.

In addition, Lilly’s senior research scientist, Lars Viktrup, testified today with ease and certainty that tadalafil is a selective PDE 5 inhibitor approved to treat BPH. Ex. A, Trial Tr. at 950:5-10. Yet Mr. Viktrup has (still) never seen the ’124 patent and was not even aware of its existence until his participation in this litigation. *Id.* at 950:11-13 (“I haven’t seen it at all.”); Dkt. 309-1, Viktrup Dep. at 47:12-14 (“Q: You’ve never seen the UroPep patent that’s being asserted in this case? A: No”). This despite Lilly admitting that it had actual notice of the patent since October 2014. Indeed, a reasonable juror could find that Lilly knew it infringed the ’124 patent, or willfully avoided learning that it did by not sharing the Larsen Letter or ’124 patent with Cialis personnel sufficiently important to bring to trial in Marshall and help Lilly with its defense of the case.

Finally, Lilly has not finished putting on its fact witnesses. But there has not been testimony (and UroPep does not expect any) that Lilly had a reasonable belief that it did not infringe. Lilly has not disclosed any such defense and has not relied on an advice-of-counsel defense in this case. And it cannot rely on the invalidity defenses it has pursued in this litigation, because there is no evidence that Lilly “reasonably believed it had a defense to infringement at the time it engaged in the infringing conduct.” *Polara Eng’g, Inc.*, 2017 WL 754609, at *12.

CONCLUSION

UroPep respectfully requests that the Court allow the jury to decide the question of willfulness. Under prevailing case law, there is sufficient evidence to support a willfulness finding by the jury.

Date: April 19, 2017

Respectfully submitted,

By: /s/ John M. Hughes

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a) on April 19, 2017. As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A).

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